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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,483	07/14/2000	Andrew M. Hoffman	21629-001	6594

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/616,483

Applicant(s)

HOFFMAN, ANDREW M.

Examiner

Mital B. Patel

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 8/28/02 have been fully considered but they are not persuasive.
2. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.
3. The Examiner would like to point out that the limitation in claim 1 with respect to "for enclosing one external nare" does not limit the device to only or just one external nare.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Crain (US 3812853).
6. **As to claim 1**, Crain teaches a drug delivery device for a mammal comprising a cup-shaped body 12 for enclosing one external nare, wherein the device does not extend into the nostril of the mammal and wherein the device does not enclose a second nare of the mammal.

7. **As to claim 3**, Crain teaches a device wherein the device does not enclose the mouth of the mammal (See Figure 3).
8. **As to claim 6**, Crain teaches a device wherein the device is adapted for use on a horse, a cow, a sheep, or a goat.
9. **As to claim 7**, Crain teaches a device wherein the device is adapted for use on a horse.
10. **As to claim 8**, Crain teaches a device wherein the cup-shaped body comprises a flexible interface for contacting the face of the mammal.
11. **As to claim 9**, Crain teaches a device wherein the interface is angled.
12. **As to claim 10**, Crain teaches a device wherein the interface is straight.
13. **As to claim 11**, Crain teaches a device wherein the device comprises a spacer holding chamber, the chamber being in communication with the cup-shaped body (See Figure 3).
14. **As to claim 12**, Crain teaches a device wherein the chamber comprises a lumen for receiving a therapeutic agent.
15. **As to claim 13**, Crain teaches a device wherein the lumen is adapted to receive an aerosol container.
16. **As to claim 14**, Crain teaches a device wherein the lumen is adapted to receive a metered-dose inhaler (MDI) canister.
17. **As to claim 15**, Crain teaches a method for preventing or treating a respiratory condition of a mammal, comprising contacting one nare of the mammal with the device of claim 1 and delivering an effective dose of a therapeutic composition through the

device in a single inhaled breath of the mammal. It should be noted the method as recited is inherent in using the device of Crain.

18. **As to claim 16**, Crain teaches a method wherein the mammal is a horse.
19. **As to claim 17**, Crain teaches a method wherein the mammal is a horse.
20. **As to claim 18**, Crain teaches a method wherein the therapeutic composition is administered in the form of a plume of aerosolized particles.
21. **As to claim 22**, Crain teaches a device wherein the device lacks a rebreathing chamber.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain in view of Foley et al (US 5988160).

24. **As to claims 4 and 5**, Crain teaches essentially all of the limitations except for wherein the device comprises a patient-actuated unidirectional inhalation valve.

However, Foley does teach a patient-actuated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Crain to include a

Art Unit: 3761

patient-actuated unidirectional inhalation valve so that air is retained for a second inhalation and medicament is not wasted.

25. Claims 19, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crain

26. **As to claims 19, 20, and 21**, Crain fails to specifically teach the limitations with respect to the particle size and the type of medicament. However, such a limitation depends on the intended user along with the intended therapy and the type of medicament used (for particle size). Furthermore, such a limitation may be arrived through routine experimentation and observation.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5765548 and US 5038769.

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

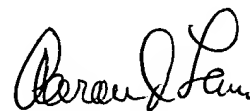
Art Unit: 3761

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Aaron J. Lewis
Primary Examiner

mbp
November 6, 2002